AVAILABILITY OF MEDICINAL PRODUCTS ON THE MALTESE MARKET AS AFFECTED BY REGULATION

Anna Maria Cassar, Anthony Serracino-Inglott
Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida

Corresponding author: Anna Maria Cassar
Email: cassar.annamaria@gmail.com

Abstract

OBJECTIVES To evaluate availability issues of medicinal products in Malta and to identify therapeutic groups for which no products are authorised or available.

METHOD An extensive review of the Malta Medicines List (March 2015) was carried out and key factors affecting availability were identified.

KEY FINDINGS An estimated average of 62% of authorised medicinal products are actually placed on the Maltese market and the lowest availability rates recorded were for authorisations made via Article 126(a) of Directive 2001/83/EC.

CONCLUSION Smaller European member states such as Malta share availability issues as regards medicinal products and initiatives should be implemented to prevent such situations from impacting public health.

KEYWORDS ATC Codes, Availability, Malta Medicines List, Medicinal Products

Introduction

The market of medicinal products in the European Union is a highly regulated area. Medicinal products are regulated differently compared to other products and placement of these products on the market is not solely the responsibility of the manufacturer. Market authorisations are granted by the regulatory authorities of member states or the European Commission (EC) after being assessed by relevant expertise. Such authorisations can however only be granted after the manufacturer has applied for them, which may lead to situations where medicinal products are not equally available in all member states.[1]

Unavailability of some medicinal products is a threat to public health and welfare since it may create problems for patients, healthcare professionals and also governments. Consequences for patients will depend on the severity of their disease or condition and the availability of therapeutic alternatives. Availability of human medicinal products on small markets such as Malta is a public health concern which requires adequate attention. The aim of the study was to evaluate availability issues of medicinal products in Malta and to identify therapeutic groups for which no products are authorised or available.

Method

This study was divided into three phases. In phase 1 review of the Malta Medicines List (March 2015) issued by the Medicines Authority (MA) outlining all medicinal products authorised in Malta was carried out. The products in this list were re-grouped according to the Anatomical Therapeutic Chemical (ATC) classification system, a system of alphanumeric codes developed by the World Health Organization for classification of drugs and other medicinal products. After grouping them according to their ATC codes, the products were further sub-divided according to their route of authorisation, namely national marketing authorisations, authorisations made via Article 126(a) of Directive 2001/83/EC2 and parallel import licenses. In phase 2 Maltese wholesale dealers were consulted to develop a database of medicinal products licensed with the MA that are subsequently placed on the local market, and phase 3 involved identification of discontinuities in the availability of medicinal products. Reasons why these

On average 62% of the products authorised in the Malta Medicines List are subsequently placed on the market and made available to patients

products were not marketed were identified and tabulated and statistical analysis of the outcomes was performed. The length and duration of each phase varied according to the response rate from marketing authorisation holders and wholesale dealers. Each phase of the study was carried out with the assistance and advice of the staff at the Licensing Directorate at the MA.

Results

On average 62% of the products authorised in the Malta Medicines List are subsequently placed on the market and made available to patients. The average availability rate for all products pertaining to ATC Code A 'Alimentary Tract and Metabolism' was 49%. Several groups in this category were found to have significantly low availability rates. In the category of products for 'bile and liver therapy' (Group A05), five products were licensed and only two of these have been placed on the market. Similarly, for 'anti-obesity preparations' (Group A08) only one product is licensed and marketed locally. For 'digestives, including enzymes' (Group A09), only two authorised products were identified, out of which only one is marketed. For 'tonics' (Group A13), three out of four products are available in Malta, and no products have been authorised for systemic use with respect to 'anabolic agents' (Group A14), For Group A15, 'appetite stimulants', one product is authorised and subsequently marketed and for 'other alimentary tract and metabolism products' (Group A16) two products have been authorised, however none have been placed on the local market.

The average availability rate for products pertaining to ATC code B 'Blood and Blood-Forming Organs' was 44%, representing the lowest average availability rate for licensed medicines recorded for all ATC codes. Only one group within this therapeutic category was considered at risk of availability problems namely 'other haematological agents' (Group B06) where three products are licensed but only two have been placed on the market. The average availability rate for products in ATC code C 'Cardiovascular System' was calculated to be 57% which is higher compared to the first two therapeutic categories. Only Group C04 for 'peripheral vasodilators' was considered to pose a potential availability problem as only two products are licensed in this category and both are marketed locally. However, at the time the study was carried out one of these products was experiencing a temporary availability problem and therefore only one medicinal product was considered available in Malta for this therapeutic group.

For ATC Code D, 'Dermatological Products', average availability rate was 69%. For both 'preparations for treatment of wounds and ulcers' (Group D03) and 'medicated dressings' (Group D09) only one product is licensed and marketed. In ATC Code G, 'Gynaecological Anti-Infectives and Antiseptics', the average availability rate was calculated to be 70% and none of the subgroups within this category were considered to run the risk of availability problems due to having significantly higher rates of marketed medicines with respect to other therapeutic codes. The average availability rate calculated for ATC Code H, 'Systemic Hormonal Preparations, excluding sex hormones and insulins', was also 70% and two subgroups were considered at risk of availability problems, namely 'pancreatic hormones' (Group H04) and 'products for calcium homeostasis' (Group H05), where for both groups only two products are licensed and marketed in Malta.

For ATC Code J, 'Anti-Infectives for Systemic Use', the average availability rate was calculated to be 57% and none of the products in this category were considered to be at risk of availability problems due to having significantly higher rates of marketed medicines with respect to other therapeutic codes. In ATC Code L, 'Antineoplastic and Immunomodulating Agents', the average availability rate of licensed medicines was 61% and no therapeutic groups in this category were considered to be at risk of availability problems. In ATC Code M, 'Musculoskeletal System', an average availability rate of 65% was noted for licensed medicines and only Group M09 'other drugs for the disorders of the musculoskeletal system' was considered to have an availability risk since only one product is placed on the local market.

An average availability rate of 66% was recorded for ATC Code N, 'Nervous System' whereas the highest recorded availability rate (78%) for licensed medicines was that for ATC Code P, 'Antiparasitic Products, Insecticides and Repellents'. Group P02, 'antihelminthics' was considered to be subject to an availability threat as only two products are licensed and marketed. For ATC code R, 'Respiratory System', an average availability rate of 61% was recorded for licensed

The general trend observed for all ATC codes was that the lowest rates of availability were recorded for authorisations made via Article 126(a) of Directive 2001/83/EC

medicines and no therapeutic groups in this category were considered to be at risk of availability problems. The availability rate for ATC code S, 'Sensory Organs', was higher at 67% and Group S03, 'ophthalmological and ontological preparations', was identified as being subject to availability risk as only one product is licensed and marketed.

For ATC Code V 'Various', the average availability rate of licensed medicines was 48%. A number of subgroups within this therapeutic group were considered to be at risk of availability issues, namely Group V01 'allergens', Group V04 'diagnostic agents' and Group V07 'all other non-therapeutic products', where no products in these groups are available locally despite some products being authorised. No products are licensed for Group V20, 'surgical dressings' and only one product is available on the market for Group V06, 'general nutrients'.

The general trend observed for all ATC codes was that the lowest rates of availability were recorded for authorisations made via Article 126(a) of Directive 2001/83/EC.[2] This could be attributed to the fact that several authorisations made via this route are submitted with the intention of placing the product in question on the national government formulary list. This is done through submission of an application in the Government tender process and if the marketing authorisation holder is not awarded the tender, the applicant may decide that it is not feasible to place the product on the Maltese market.

Discussion

Smaller EU member states share some common and general availability problems. These countries generally do not have a local research and development based pharmaceutical industry and this, together with the fact that they are considered economically unattractive countries, may deter their inclusion as reference or concerned member states in mutual recognition or decentralised procedures. Moreover, although smaller member states are selected in these procedures, the launch of the product on the local market may not occur post-authorisation for a number of reasons, such as labelling in the national language.[1,3]

The size of the market and its national language are closely related. Article 63 of Directive 2001/83/EC specifies the requirement of having the labelling and package leaflet translated into a country's national language. While this is not considered to be a problem for larger markets, it may be thought to unfeasible for smaller markets. Moreover, pharmaceutical companies may not be willing to accept the extra costs involved, such as setting up of a pharmacovigilance network for markets that cannot sustain profitability.

Repackaging facilities are easily available in all member states and the packaging site in charge of the repackaging operation should be registered in the marketing authorisation application and should perform the activities in accordance to GMP requirements. However, some marketing authorisation holders may refuse to use them either since these may incur a comparatively higher additional cost or potentially due to a company's policy that prohibits the handling of the pharmaceutical product by third parties. Overlabelling or affixing stickers with a different language on packaging may decrease such costs, however this is only applicable for products authorised via parallel distribution or for an emergency situation, such as a product supply shortage.

The introduction of country-specific information in labelling or product information, such as blue-box requirements, may decrease the motivation of a pharmaceutical company to make its product available on a small market. In an effort to counteract this, Malta has not introduced any such blue-box requirements to eliminate this burden on marketing authorisation holders.

Unavailability of medicinal products has been identified as a problem and a priority issue, particularly for member states with small markets such as Malta

Conclusion

Unavailability of medicinal products has been identified as a problem and a priority issue, particularly for member states with small markets such as Malta. The potential detrimental effect that this may have on public health can sometimes be overlooked and health needs and requirements of all citizens from all member states within the EU need to be considered and protected. This is not always compatible with the needs and requirements of the pharmaceutical industry when applicants are to choose suitable markets for their products. Initiatives have been launched to improve the availability situation however, this has not always proved effective as these initiatives are not accompanied by an obligation to market. The choice of whether products are placed on a particular market should not depend solely on business feasibility and appropriate solutions to this problem can only be achieved through discussion and collaboration at high level between the EC, member states and stakeholders.

References

1. Heads of Medicines Agencies (HMA). Availability of Human Medicinal Products: Report of Task Force of HMA MG. Madeira (Portugal): HMA;2007.
2. European Commission (EC). Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use [Online]. Official Journal of the European Union 2004;136:34-57 [cited 2016 Feb 3]. Available from: URL: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2004_27/dir_2004_27_en.pdf
3. Traulsen JM, Almarsdottir AB. The argument for pharmaceutical policy. Pharm World Sci. 2005;27:7-12